Charles M. Lizza
William C. Baton
Sarah A. Sullivan
SAUL EWING ARNSTEIN & LEHR LLP
One Riverfront Plaza, Suite 1520
Newark, NJ 07102-5426
(973) 286-6700
clizza@saul.com
wbaton@saul.com

Attorneys for Plaintiff
Corcept Therapeutics, Inc.

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

CORCEPT THERAPEUTICS, INC., **Plaintiff,** **v.** **TEVA PHARMACEUTICALS USA, INC.,** **Defendant.**	Civil Action No. 18-3632 (JXN)(LDW) (consolidated) [redacted] Hon. Julien Xavier Neals, U.S.D.J. Hon. Leda D. Wettre, U.S.M.J. (Filed Electronically)

CORCEPT'S REPLY IN FURTHER SUPPORT OF ITS MOTION FOR SUMMARY JUDGMENT OF INFRINGEMENT OF U.S. PATENT NO. 10,195,214 AND OPPOSITION TO DEFENDANT'S CROSS-MOTION FOR SUMMARY JUDGMENT

TABLE OF CONTENTS

TABLE OF EXHIBITS

Short Citation*	Full Citation	Exhibit Letter
SMF	Local Civil Rule 56.1 Statement of Undisputed Material Facts	
'214 Patent	U.S. Patent No. 10,195,214	A
2012 Korlym® Label	2012 Korlym® Full Prescribing Information (CORMIFE-T-00002807-29)	B
2019 Korlym® Label	2019 Korlym® Full Prescribing Information (CORMIFE-T-00062787-809)	C
CDC	"Treatment for Aspergillosis," Centers for Disease Control and Prevention (Jan. 8, 2021), https://www.cdc.gov/fungal/diseases/aspergillosis/treatment.html	D
Charmandari	E. Charmandari et al., "Adrenal insufficiency," *Lancet*, 383(9935):2152-67 (2014) (CORMIFE-T-00011065-80)	E
Cuevas-Ramos	D. Cuevas-Ramos et al., "Update on medical treatment for Cushing's disease," *Clin. Diabetes & Endocrinol.*, 2:16 (2016) (TEVA_MIFE-0071171-83)	F
Dang	C.N Dang, et al., "Pharmacological Management of Cushing's Syndrome: An Update," *Arq. Bras. Endocrinol. Metab.*, 51(8):1339-1348 (2007) (TEVA_MIFE-0071205-214)	G
DeRosa Tr.	Gregg DeRosa Deposition Transcript (July 2, 2020)	H
FDA Approval Letter	Korlym® FDA Approval Letter (CORMIFE-T-00068874-80)	I
February Letter	February 18, 2021 Letter from Teva to the Honorable Leda D. Wettre, U.S.M.J.	J
Fleseriu 2012	M. Fleseriu et al., "Mifepristone, a Glucocorticoid Receptor Antagonist, Produces Clinical and Metabolic Benefits in Patients with Cushing's Syndrome," *J. Clin. Endocrinol. Metab.*, 97(6):2039-49 (2012) (TEVA_MIFE-0071355-65)	K

Short Citation*	Full Citation	Exhibit Letter
Fleseriu 2013(a)	M. Fleseriu & S. Petersenn, "New avenues in the medical treatment of Cushing's disease: corticotroph tumor targeted therapy," *J. Neurooncol.*, 114:1-11 (2013) (TEVA_MIFE-0071376-86)	L
Fleseriu 2013(b)	M. Fleseriu et al., "A New Therapeutic Approach in the Medical Treatment of Cushing's Syndrome: Glucocorticoid Receptor Blockade with Mifepristone," *Endocrine Practice*, 19(2):313-26 (2013) (TEVA_MIFE-0071387-400)	M
Guelho	D. Guelho & A.B. Grossman, "Emerging drugs for Cushing's disease," *Expert Opin. Emerging Drugs*, 20(3):463-78 (2015) (TEVA_MIFE-0071474-90)	N
Itraconazole Label	Sporanox® (Itraconazole) Full Prescribing Information (CORMIFE-T-00010651-721)	O
Mayo Clinic	"Hyperglycemia in Diabetes," The Mayo Clinic (Nov. 3, 2018), https://www.mayoclinic.org/diseases-conditions/hyperglycemia/ symptoms-causes/syc-20373631	P
Morgan	F.H. Morgan & M.J. Laufgraben, "Mifepristone for Management of Cushing's Syndrome," *Pharmacotherapy*, 33(3):319-29 (2013) (TEVA_MIFE-0071741-51)	Q
OCP Memo	U.S. Food and Drug Administration, Office of Clinical Pharmacology Review Memorandum Addendum (January 20, 2012) (CORMIFE-T-00068918-20)	R
Oosterhuis	J.K. Oosterhuis et al., "Life-threatening *Pneumocystis jiroveci* pneumonia following treatment of severe Cushing's syndrome," *Netherlands J. Med.*, 65(6):215-17 (2007) (CORMIFE-T-00011108-10)	S
Pivonello	R. Pivonello et al., "The Treatment of Cushing's Disease," *Endocrine Reviews*, 36(4):385-486 (2015) (TEVA_MIFE-0071863-964)	T

Short Citation*	Full Citation	Exhibit Letter
Teva Label	Teva Mifepristone Tablets Full Prescribing Information (TEVA_MIFE-0120842-61)	U
Viera	A.J. Viera & N. Wouk, "Potassium Disorders: Hypokalemia and Hyperkalemia," *Am. Family Physician*, 92(6):487-95 (2015)	V
Belanoff Tr.	Dr. Joseph Belanoff Deposition Transcript (October 15, 2020)	W
Dobs Tr.	Dr. Adrian Dobs Deposition Transcript (April 16, 2021)	X
Hamrahian Tr.	Dr. Amir Hamrahian Deposition Transcript (May 7, 2021)	Y
Snyder Tr.	Dr. Peter Snyder Deposition Transcript (May 20, 2021)	Z

* All Exhibits cited herein are referred to by their "Short Citation." Exhibits A-V were attached to the Declaration of Nicholas A. LoCastro submitted in support of Corcept's Motion for Summary Judgment of Infringement of U.S. Patent No. 10,195,214 (Dkt. 198-01). Exhibits W-Z are attached to the Second Declaration of Nicholas A. LoCastro, submitted herewith.

TABLE OF AUTHORITIES

Page

Cases

Statutory Authorities

I. INTRODUCTION

In this pharmaceutical patent case arising under the Hatch-Waxman Act, Plaintiff Corcept Therapeutics, Inc. ("Corcept") moved for summary judgment of infringement of U.S. Patent No. 10,195,214 ("the '214 Patent") on the basis that the Defendant's package insert induces infringement of the methods claimed in the '214 Patent. Specifically, the Defendant's package insert—i.e., the prescribing information it intends to distribute with its generic drug product—(1) instructs healthcare professionals that the methods of treatment claimed in the '214 Patent are both "necessary" and "required" in specific circumstances and (2) contains clinical trial data indicating that those claimed methods are safe for their patients. In opposition to Corcept's motion, Defendant Teva Pharmaceuticals USA, Inc. ("Teva") does not dispute the content of its package insert, does not dispute that the "necessary" and "required" instructions set forth therein directly overlap with the claimed methods, and does not meaningfully challenge any other material fact that supports Corcept's motion. *See generally*, Teva Reply to Corcept SMF (ECF No. 202-1). Instead, rather than address the factual record, Teva relies on an overbroad reading of a single Federal Circuit case to assert that summary judgment of non-infringement should be granted in its favor. But under Teva's interpretation of that case, no package insert could ever be relied upon to demonstrate induced infringement under the Hatch-Waxman Act. This of course is not the law; more than a decade of Federal Circuit precedent supports the straightforward principle that where, like here, a package insert encourages healthcare professionals to perform the claimed method, the defendant has the requisite intent to induce infringement.

In this case, under that long-standing Federal Circuit precedent, the Court should find as a matter of law and based on the undisputed factual record that Teva has the requisite intent to induce infringement of the '214 Patent. The '214 Patent claims methods of co-administering 600 mg of the drug mifepristone with strong CYP3A inhibitors. Before the invention of the claimed

methods, persons of skill in the art would ***not*** "have expected co-administration of more than 300 mg of mifepristone with a strong CYP3A inhibitor to be safe for the treatment of Cushing's syndrome or related symptoms in patients." *Teva Pharmaceuticals USA, Inc. v. Corcept Therapeutics Inc.*, PGR2019-00048, 2020 WL 6809812, at *22 (P.T.A.B. Nov. 18, 2020).[1] Following the issuance of the '214 Patent, Teva updated its proposed package insert to include clinical trial data and corresponding dosing instructions indicating that the co-administration of mifepristone and strong CYP3A inhibitors ***is safe***, so long as healthcare professionals follow the "required" "[d]ose adjustment" set forth in the package insert. *See* SMF at ¶¶ 30-32. Those required dose adjustment steps indisputably track each step of the methods claimed in the '214 Patent, including reducing the mifepristone dose from an original dose of 900 mg/day to an adjusted dose of 600 mg/day. SMF at ¶ 27. The law is clear that the Court may infer Teva's intent to encourage infringement based upon these undisputed facts.

Rather than identify a single disputed *fact* that would defeat Corcept's motion, Teva instead misinterprets the *HZNP* case to argue that induced infringement (1) is not possible if a package insert operates in an "*if-then*" manner and (2) requires that following the package insert will *always* result in infringement. Teva's arguments are not only unsupported by the *HZNP* case itself, but also flatly inconsistent with Federal Circuit precedent. Moreover, Teva does not address or acknowledge the existence of the clinical data in the package insert, which instructs healthcare professionals that mifepristone can be safely co-administered with strong CYP3A inhibitors by following the "required" dose adjustment steps—which indisputably track each step of the claimed methods. These undisputed facts, which Teva does not discuss, lead to a finding that as a matter of law, Teva has the requisite intent to induce infringement.

[1] Teva is statutorily estopped from contesting this fact at trial. *See* 35 U.S.C. § 325(e)(2).

II. ARGUMENT

A. Teva's Opposition And Cross-Motion Is Premised On Two Misstatements Of Law

1. *HZNP* Did Not Change the Law to Allow Infringers to Escape Inducement Liability By Characterizing a Package Insert As Providing "*If / Then*" Instructions

"Whoever actively induces infringement of a patent shall be liable as an infringer." 35 U.S.C. § 271(b). When deciding questions of induced infringement in Hatch-Waxman cases, courts routinely look to the instructions set forth in the generic drug product's package insert, which is also often referred to as a label or labelling, to ascertain whether the label encourages, promotes, or recommends that healthcare providers use the generic product in a manner that is covered by the claims of an asserted patent. *See, e.g.*, *Sanofi v. Watson Laboratories Inc.*, 875 F.3d 636, 646 (Fed. Cir. 2017) (holding that "[t]he content of the label … permits the inference of specific intent to encourage the infringing use."). "In the Hatch–Waxman context, statements in a package insert that encourage infringing use of a drug product are alone sufficient to establish intent to encourage direct infringement for purposes of inducement to infringe under 35 U.S.C. § 271(b)." *Bone Care Int'l, LLC. v. Roxane Labs., Inc.*, No. 09-285, 2012 WL 2126896, at *9 (D. Del. June 11, 2012) (citation and quotations omitted). The law is also well-established that information in a package insert may be found to encourage an infringing use where it plainly instructs healthcare professionals to practice the claimed method. *See, e.g.*, *AstraZeneca LP v. Apotex, Inc.*, 633 F.3d 1042, 1060 (Fed. Cir. 2010) ("The pertinent question is whether the proposed label instructs users to perform the patented method"); *Braintree Labs. v. Breckenridge Pharm., Inc.*, 688 F. App'x 905, 910 (Fed. Cir. 2017) ("Because Breckenridge's ANDA label 'instruct[s] how to engage in an infringing use, [it] show[s] an affirmative intent that the product be used to infringe.'" (alteration in original)). The cases cited in Teva's cross-motion agree with

this well-established principle. *See, e.g.*, *Shire LLC v. Amneal Pharm., LLC*, No. 11-3781, 2014 WL 2861430, at *4 (D.N.J. June 23, 2014) ("[T]he central question here is whether the label instructs people to use [the claimed method]."); *United Therapeutics Corp. v. Sandoz, Inc.*, No. 12-1617, 2014 WL 4259153, at *15 (D.N.J. Aug. 29, 2014).

As set forth in Corcept's opening memorandum of law, the undisputed facts demonstrate that Teva's proposed package insert will encourage healthcare providers to practice the claimed methods, and the Court may therefore infer Teva's intent as a matter of law. Teva's proposed package insert indisputably instructs: (1) there will be instances where it is "necessary" to co-administer mifepristone and strong CYP3A inhibitors; (2) adjusting the mifepristone dose is "required" when co-administering mifepristone and strong CYP3A inhibitors; (3) how to specifically adjust the mifepristone dose, which directly reads on the claimed methods of treatment; and (4) it is safe to co-administer mifepristone and strong CYP3A inhibitors when following the "required" dosage adjustments. ECF No. 198 at §§ IV(A)(1)-(4). In opposition to Corcept's motion, Teva does not dispute the content of its package insert, nor does it meaningfully challenge any of the facts set forth in the SMF. *See* Teva Reply to Corcept SMF. In fact, Teva does not expressly identify a single factual dispute that would preclude the entry of summary judgment. Instead, Teva opposes Corcept's motion—and supports its own cross-motion—through attorney argument that contorts Federal Circuit precedent.

Teva's opposition and cross-motion centers on the fabricated argument that it is "black-letter law" that a package insert "instruction in the form '*if* you do X, *then* do Y' is *not* an instruction to do X." Teva Br. at 1; *see also id*. at 11.[2] To support this argument, Teva relies on

[2] As used herein, "Teva Br." refers to Defendant Teva Pharmaceuticals USA, Inc.'s Brief in Opposition to Corcept's Motion for Summary Judgment of Infringement of U.S. Patent No.

HZNP Medicines LLC v. Actavis Labs. UT, Inc., 940 F.3d 680 (Fed. Cir. 2019). But *HZNP* did not create an "*if/then*" exception to induced infringement. Contrary to Teva's assertion, the *HZNP* decision did not change the law of induced infringement and is entirely consistent with long-standing precedent that the question for district courts to consider when determining whether a proposed generic drug label will induce infringement is whether the label will encourage, recommend, or promote practicing the claimed methods. *See, e.g.*, *Sanofi*, 875 F.3d at 644 ("When proof of intent to encourage depends on the label accompanying the marketing of a drug, '[t]he label must encourage, recommend, or promote infringement.'"). *HZNP* itself states, "[i]n ANDA cases, when a plaintiff attempts to draw intent from the label, we examine whether the proposed label 'encourage[s], recommend[s], or promote[s] infringement.'" 940 F.3d 701-02 (alteration in original).

There is no specific formula for finding encouragement or recommendations to infringe within proposed generic labels. The Federal Circuit "has repeatedly explained that, for the finder of fact to find the required intent to encourage, '[w]hile proof of intent is necessary, direct evidence is not required; rather, circumstantial evidence may suffice.'" *See Sanofi*, 875 F.3d at 644 (citation omitted). Sufficient circumstantial evidence has been found in various ways, including where the proposed generic label contains (1) instructions on how to perform the claimed methods and (2) clinical data evidencing the benefits of the claimed methods. *See id.* at 645 (finding encouragement to induce where the label "directs medical providers to [clinical study data] identifying the desired benefit for only patients with the patent-claimed risk factors"); *Vanda Pharm. Inc. v. West-Ward Pharm. Int'l Ltd.*, 887 F.3d 1117, 1131 (Fed. Cir. 2018) (finding encouragement to induce where data in the label "constitutes a recommendation"

10,195,214 and in Support of Cross-Motion for Summary Judgment of Non-Infringement of U.S. Patent No. 10,195,214 (ECF No. 202).

to perform the claimed methods); *Amarin Pharma, Inc. v. Hikma Pharm. USA Inc*., 449 F. Supp. 3d 967, 1000 (D. Nev. 2020) (finding encouragement to induce where clinical trial data would recommend to "doctors to prescribe the applicable drug in [an infringing manner].").

HZNP did not overturn the Federal Circuit's longstanding practice of evaluating each Hatch-Waxman induced infringement case on its own facts, including by looking to the specific contents of the package insert at issue. Nor could the *HZNP*, split three-judge panel have done so. Federal Circuit "panels do not have the authority to overrule prior precedential panel decisions unless the *en banc* court or the Supreme Court overturns the prior decision." *Diamond Coating Techs., LLC v. Hyundai Motor Am.*, 823 F.3d 615, 621 (Fed. Cir. 2016).

Regardless, the *HZNP* panel also did not establish an "if/then" exception to the law of induced infringement. Such a rule would preclude any future finding of induced infringement for ***any*** method of treatment patents. Teva thus admits, as it must, that "[i]t is surely true that drug labels do not *require* physicians to do anything—the physician can always choose not to follow the label." Teva Br. at 14. Accordingly, every single package insert could have an "if/then" interpretation—***if*** the physician (following his training and exercising his medical judgment) chooses to administer the particular drug to treat a condition described in the package insert, ***then*** the physician should follow the instructions. The induced infringement inquiry is not determined based on semantics; the question is not, nor has it ever been, whether the package insert operates in an if/then manner, a when/then manner, or uses some other incantation of magic words. Instead, the Federal Circuit has made clear numerous times over the past decade that district courts are to consider the totality of the package insert and determine whether the information—including the dosing instructions and data—contained therein would encourage doctors to perform the patented method. *See AstraZeneca*, 633 F.3d at 1060 ("The pertinent

question is whether the proposed label instructs users to perform the patented method"); *accord Eli Lilly & Co. v. Teva Parenteral Medicines, Inc.*, 845 F.3d 1357, 1368-69 (Fed. Cir. 2017); *Sanofi*, 875 F.3d at 646; *Braintree Labs.*, 688 F. App'x at 910; *Vanda Pharm.*, 887 F.3d at 1132.[3]

Accordingly, the *HZNP* panel described the non-infringing package insert in that case as operating in an "if/then" manner. *See* 940 F.3d at 702 ("*if* the user wants to cover the treated area with clothing or apply another substance over it, then the patient should wait until the area is dry."). But the key to the finding in *HZNP* is that the label in that case provided no encouragement to do the "*if*" step—i.e., nothing in the label actually encouraged patients to cover the affected area with anything else, much less the specific ointments required by the claims. Instead, it was entirely up to the patient whether to ever perform the "*if*" step; i.e., to apply sunscreen or bug spray after applying their topical medicine, and there was no evidence, much less clinical data, in the package insert indicating that the patient would ever actually perform that third step. *Id.* The Federal Circuit therefore held that the label did not encourage infringement of the claimed three-step method.

In this case, on the other hand, there is no dispute that Teva's package insert instructs that the patented "[d]ose adjustment" methods are "required" when "necessary" to co-administer mifepristone with strong CYP3A inhibitors. *See* Teva Reply to Corcept SMF at ¶¶ 24, 27, 29, 32. More specifically, there is no dispute that Section 2.5 of Teva's proposed package insert instructs that mifepristone should be used in combination with strong CYP3A inhibitors "when necessary" to do so. *Id.* at ¶ 24. It is further undisputed that Section 2.5 provides "[d]ose

[3] For this reason, the taxicab analogy that Teva invokes on the first page of its brief, while colorful, misses the point. The Court need not undertake an exercise in semantics to determine, in the abstract, the meaning of "if/then" instructions. Instead, the package insert should be viewed as a whole to determine whether the language, instructions, and data contained therein would encourage doctors to practice the claimed methods.

adjustment" steps for physicians to follow "when [a] strong CYP3A inhibitor is added" to the treatment regimen of a patient "already being treated with mifepristone tablets." *Id.* There is no dispute that Section 2.5 further instructs physicians that they should review Sections 5.6 and 7.2, which provide additional information on the interaction between mifepristone and strong CYP3A inhibitors. *Id.* There is no dispute that each of these sections direct physicians to review Section 12.3, which contains a table ("Table 3") entitled, "Summary Table of Mifepristone Drug-Drug-Interaction Effects." *Id.* at ¶ 32. And there is no dispute that Table 3 provides clinical data regarding the rise in mifepristone concentrations that result from co-administration with the strong CYP3A inhibitors ketoconazole and itraconazole, and instructs that a "**[d]ose adjustment** [is] **required**" when co-administering mifepristone with strong inhibitors. *Id.* Finally, there is no dispute that these "required" dose adjustment steps (1) are set forth in Section 2.5 of the Teva package insert and (2) directly track the methods of treatment claimed in the '214 Patent. Thus, as illustrated below, the undisputed facts of this case are very different than *HZNP*:

	Teva Label	**HZNP Label**
Instruction that it would ever be "necessary" to perform patented method	Yes – SMF at ¶ 29.	No. And the Court rejected the argument that sources outside the label indicated that "application of sunscreen is medically necessary." 940 F.3d at 701.
Direct overlap between patented method and label instructions	Yes – *compare* SMF at ¶ 10 with *id.* at ¶ 27.	No. "[The] label is broader than … claimed method." *Id.* at 702.
Instruction that it would ever be "required" to perform patented method	Yes – SMF at ¶ 32.	No. "[The] label does not require subsequent application of sunscreen, insect repellant, or a second medication." *Id.*
Clinical data indicating claimed methods are safe	Yes – SMF at ¶ 32.	No.

The Court can therefore find as a matter of law that the instructions and clinical data in Teva's package insert will provide encouragement and recommendations for healthcare professionals to practice the claimed methods. *See, e.g.*, *Sanofi*, 875 F.3d at 645 (finding encouragement to induce where the label "directs medical providers to [clinical trial] information identifying the desired benefit for only patients with the patent-claimed risk factors"); *Vanda*, 887 F.3d at 1131 (finding encouragement to induce infringement where pharmacokinetic data "constitutes a recommendation" to perform the claimed methods).

Further, Teva does not dispute that in each of the Federal Circuit cases cited in Corcept's opening memorandum, the Court properly "held that an ANDA applicant's label language induced infringement." *See* Teva Br. at 20. The Federal Circuit's holding in one of these cases, *Vanda*, further illustrates that *HZNP* did not create a special "if/then" exception to induced infringement. In *Vanda*, the patent claimed a method of treating schizophrenia in patients who were poor metabolizers of the enzyme CYP2D6 by: (i) testing the patient to determine whether she was a poor metabolizer, and (ii) administering an iloperidone dosage of 12 mg/day or less for poor metabolizers and 12–24 mg/day for non-poor metabolizers. *See* 887 F.3d at 1121; *see also* Teva Br. at 20. The defendant's proposed label instructed physicians to administer "12 to 24 mg/day" iloperidone and further instructed that "the 'iloperidone dose should be reduced by one-half for poor metabolizers of CYP2D6.'" *See* 887 F.3d at 1122; *see also* Teva Br. at 20. In other words, the proposed package insert in *Vanda* instructed that ***if*** a physician decided to treat a poor metabolizer of CYP2D6 with iloperidone, ***then*** the physician should reduce the dose by half. *See* 887 F.3d at 1122. Nothing in the label ***required*** physicians to treat poor metabolizers of CYP2D6; a prescriber could administer iloperidone according to the instructions in the proposed label at issue in the *Vanda* case without ever administering the drug to a poor CYP2D6

metabolizer, and therefore without ever infringing the asserted patent. *See id.* But the Federal Circuit found that the proposed label nonetheless encouraged infringement, because if physicians have a need to administer the drug to poor metabolizers of CYP2D6, then the applicable dosing instructions overlapped with—and directed physicians to practice—the patented method. *Id.* at 1132. In other words, just like Teva's label in this case, the package insert in *Vanda* instructed and encouraged physicians to carry out the "if" step when necessary to do so. In finding intent to induce infringement, the Federal Circuit noted, "[e]ven if not every practitioner will prescribe an infringing dose, that the target dose range instructs users to perform the patented method is sufficient to provide evidence of [the defendant's] affirmative intent to induce infringement." *Id.* (citations and internal quotations omitted).

The same logic applies here. Even if not all physicians will co-administer mifepristone with strong CYP3A inhibitors, the undisputed fact that the proposed label instructs physicians to practice the claimed methods when necessary to co-administer the two drugs is sufficient evidence of Teva's affirmative intent to induce infringement. *Id*. And the evidence of Teva's intent to induce is even stronger here than it was in *Vanda*, in view of the package insert's teachings that there are instances where it will be "necessary" to co-administer, that physicians are "required" to practice the claimed methods in such instances, and that the claimed methods are safe. Accordingly, Teva's position that any package insert that provides an "if/then" instruction cannot induce infringement, as a matter of law, is meritless.

2. There Is No Requirement that Following the Package Insert Must *Necessarily* Result In Infringement Every Time the Drug Is Prescribed

Teva next attempts to evade the binding precedent cited in Corcept's opening memorandum (and above) by manufacturing a requirement that induced infringement can be found only if following a package insert will "necessarily result in infringement." *See* Teva Br.

at 23. In other words, Teva argues that 100% of a drug's use according to its package insert must infringe for there to be induced infringement. *See id.* at 21 (arguing *AstraZeneca* is inapplicable because prescribing Teva's generic product on-label will not "necessarily result in infringement"); *id.* at 22-23 (arguing *Braintree* does not apply because Teva's package insert "does not necessarily result in infringement when the FDA-approved indication is followed.").

Teva again misstates the law. As with Teva's erroneous "if/then" argument, the Federal Circuit's decision in *Vanda* is instructive. In *Vanda*, a physician following the proposed generic label could choose to prescribe the drug iloperidone to a schizophrenic patent who was a poor metabolizer of the enzyme CYP2D6, or the physician could choose to prescribe iloperidone to a patient who metabolized CYP2D6 normally. *See* 887 F.3d at 1121-22. The patented method involved the treatment of schizophrenia in patients who were poor metabolizers of the enzyme. *Id.* Therefore, physicians could prescribe generic iloperidone to patients who were not poor metabolizers, follow the instructions in the proposed label to the letter, and never infringe. The Federal Circuit made clear that this did not preclude a finding of infringement, because there is no requirement, as Teva claims, that a package insert must "necessarily result in infringement when the FDA-approved indication is followed." The Court held in *Vanda*, "[e]ven if not every practitioner will prescribe an infringing dose," the question is whether the language in the package insert nonetheless "constitutes a recommendation to perform [the claimed method]" when it is medically appropriate to do so. 887 F.3d at 1131-32. In other words, it is "irrelevant that some users may not specifically perform the patented method." *Forest Labs Holdings Ltd. v. Mylan Inc.*, 206 F. Supp. 3d 957, 977 (D. Del. 2016). Teva's second attempt to re-write the law on induced infringement should also be rejected.

B. Teva's Attempts to Mischaracterize the Factual Record Do Not Defeat Corcept's Motion for Summary Judgment

Applying the undisputed facts to the appropriate legal standard set forth above (*supra* at § II(A)(1) and in Corcept's opening memorandum of law (*see* ECF No. 198 at § III(B)), it is clear that, as a matter of law, the undisputed content of Teva's package insert provides sufficient evidence of Teva's intent to induce infringement. Rather than point to any specific factual dispute that would preclude the entry of summary judgment under the appropriate legal standards, Teva instead relies on four lines of attorney argument that mischaracterize the record. None of these arguments defeat Corcept's motion for summary judgment, let alone support granting Teva's cross-motion.

1. The Prosecution History's Discussion of an Outdated Version of the Package Insert Does Not Create a Disputed Issue of Material Fact

Teva points to portions of the '214 Patent's prosecution history—the back and forth between Corcept and the U.S. Patent Office leading to the issuance of the '214 Patent—to claim that "Corcept characterized … an earlier version of the Korlym label as teaching skilled artisans 'to avoid use of mifepristone with CYP3A inhibitors.'" *See* Teva Br. at 9. More accurately, the "earlier version" of the Korlym® package insert (from 2012) referenced in the prosecution history taught skilled artisans to avoid the use of ***more than 300 mg*** of strong CYP3A inhibitors with mifepristone. And Teva ignores that the 2012 package insert is materially different than the current package insert Teva will distribute with its generic mifepristone product. Korlym® obtained FDA approval in 2012, seven years ***before*** the issuance of the '214 Patent. *See* SMF at ¶ 3. When Korlym® was first approved—and until the invention of the '214 Patent—persons of skill in the art would not "have expected co-administration of more than 300 mg of mifepristone with a strong CYP3A inhibitor to be safe for the treatment of Cushing's syndrome or related symptoms in patients." *See Teva Pharmaceuticals*, 2020 WL 6809812, at *22. Accordingly, the

2012 version of the Korlym® package insert warned that "Korlym should be used with ***extreme caution*** in patients taking ketoconazole and other strong inhibitors of CYP3A" and "in such cases the dose should be ***limited to 300 mg per day***." 2012 Korlym® Label at 6 (emphasis added). The 2012 version of the package insert did not contain any clinical data indicating the combination was safe; to the contrary, persons of skill in the art would have thought the combination was unsafe at mifepristone doses above 300 mg.

Years after Korlym® obtained FDA approval, Corcept initiated a series of clinical trials involving the co-administration of mifepristone and certain strong CYP3A inhibitors. *See* SMF at ¶ 6. These studies revealed that the combination of 600 mg mifepristone with strong CYP3A inhibitors was actually safe to co-administer. *See id.* at ¶¶ 7-8. Clinical safety data from these studies are now reported in the current Korlym® package insert (the same data are also in Teva's materially identical package insert), and the current package insert no longer contains the warning that "***extreme caution***" should be used when co-administering mifepristone with strong CYP3A inhibitors. *See* 2019 Korlym® Label at 6, 16-17. The current Korlym® package insert (and Teva's package insert) also removes the 300 mg dosage limit and expressly provides instructions to healthcare professionals on how to administer 600 mg or 900 mg mifepristone concomitantly with a strong CYP3A inhibitor, depending on specific patient circumstance. *See, e.g.*, SMF at ¶ 27. Accordingly, Teva's attempt to argue that its current package insert will not encourage infringement based upon Corcept's characterization of the materially different 2012 Korlym® package insert is not relevant and lacks merit.

2. Teva's Suggestion that Clinicians Have Not Yet Practiced the Claimed Methods Is Legally Irrelevant and Factually Misleading

Teva next argues that because Corcept's infringement expert, Dr. Carroll, "has *never* co-administered mifepristone and a strong CYP3A inhibitor," its package insert cannot be found to

encourage infringement. *See* Teva Br. at 9. Teva goes so far as to accuse Corcept of "arguing that Teva will actively induce physicians to do something that treating physicians virtually *never do*." *Id.* at 10. This argument is both legally irrelevant and factually misleading.

With respect to the law, it is well-established that the Federal Circuit has never "required evidence regarding the general prevalence of the induced activity" in a Hatch-Waxman case. *Eli Lilly & Co.*, 845 F.3d at 1368; *accord Vanda*, 887 F.3d at 1130 ("patentees in Hatch-Waxman litigations asserting method patents do not have to prove that prior use of the NDA-approved drug satisfies the limitations of the asserted claims."). Therefore, it is of no moment that Corcept's expert has not yet personally co-administered mifepristone with strong CYP3A inhibitors. The infringement inquiry in a Hatch-Waxman case is instead forward-looking and "limited to an analysis of whether what the generic drug maker is requesting authorization for in the ANDA would be an act of infringement if performed." *Vanda*, 887 F.3d at 1130 (citation and quotation omitted).

With respect to the facts, Teva's argument is misleading at best. As an initial matter, Teva points to the fact that Dr. Carroll has treated Cushing's syndrome patients for the past 11 years as evidence that its label will not encourage doctors to practice the claimed methods. *See* Teva Br. at 9-10. This argument obscures that the '214 Patent issued only two and a half years ago (in February 2019), and that the Korlym® label was not updated to include all relevant safety data from Corcept's drug-drug interaction trials until November 2019. *See* '214 Patent at Cover; 2019 Korlym® Label at 1. Considering the rarity of Cushing's syndrome, that Dr. Carroll has not yet treated a patient who has required both mifepristone and a strong CYP3A inhibitor in the last two years is neither surprising nor a basis to conclude that doctors will "virtually never" need to co-administer these drugs in the future.

Moreover, Teva ignores and does not dispute that other experts in this action, including one of its own experts (a clinical endocrinologist, Dr. Adrian Dobs), testified that they have prescribed mifepristone with strong CYP3A inhibitors. Dr. Dobs testified in no uncertain terms that she *has* combined mifepristone with ketoconazole (a strong CYP3A inhibitor) "two to three times." Dobs Tr. at 30:18-24.[4] Dr. Dobs agreed that "mifepristone and ketoconazole can act in a complementary way to reduce the overall effect of cortisol in the human body," and that there are "instances where it may be ***necessary*** to take advantage of mifepristone and ketoconazole's dual mechanisms of action to reduce cortisol and bring a benefit to the patient." *Id.* at 30:25-32:2 (emphasis added). Another expert in this case, Dr. Amir Hamrahian, also recalls instances where he has combined mifepristone with strong CYP3A inhibitors. *See* Hamrahian Tr. at 86:6-12. Teva ignores this testimony as well. Accordingly, while Teva may wish to characterize the co-administration of mifepristone and strong CYP3A inhibitors for the treatment of Cushing's syndrome as "something that treating physicians virtually *never do*," this argument is contradicted by the expert testimony. Teva's argument is also contradicted by its own statements made before the Federal Circuit in connection with the validity of the '214 Patent. *See, e.g.*, Appellant's Principal Brief, *Teva Pharmaceuticals USA, Inc. v. Corcept Therapeutics, Inc.*, No. 21-1360, ECF No. 9 at 26 (Fed. Cir. Mar. 12, 2021) (Teva asserting that the prior art taught "mifepristone was likely to be used in conjunction with ketoconazole because ketoconazole was commonly 'used in the management of Cushing's disease.'").

[4] Teva's expert also readily agreed that Cushing's syndrome is a "rare endocrine disorder." Dobs Tr. at 21:17-19. In her 25 to 30 year career, she has treated on average 3-4 patients with Cushing's syndrome per year. *See id.* at 21:2-12.

3. Statements Made By the Inventor of the '214 Patent *Before* His Invention Do Not Create a Disputed Material Factual Issue

Teva also relies on statements that the inventor of the '214 Patent (Dr. Joseph Belanoff) made on a recorded phone call with Corcept investors in January 2016 to support its position that physicians will not perform the claimed methods. *See* Teva Br. at 10 (quoting Teva Ex. 2 at CORMIFE-T-00039366–67). Teva fails to account for the undisputed fact that Dr. Belanoff's statements were made in 2016, years ***before*** the '214 Patent issued and ***before*** the Korlym® label was updated to include the clinical safety data related to the co-administration of mifepristone and strong CYP3A inhibitors and instructions on how to co-administer. As set forth above, the original, 2012 Korlym® label in effect at the time of Dr. Belanoff's comments is materially different than the current Korlym® label (as well as the current Teva proposed package insert) and irrelevant to Teva's infringement. It makes perfect sense that Dr. Belanoff was "not seeing people use [Korlym and ketoconazole] together" based on the original Korlym® label, and prior to the publication of the clinical data indicating that this particular combination is in fact safe. Teva also takes Dr. Belanoff's statements out of context and ignores his deposition testimony, in which Dr. Belanoff explained that although he does not believe patients are "treated with Korlym® and ketoconazole simultaneously de novo," i.e., at the outset of their treatment for Cushing's syndrome, he testified—consistent with Dr. Dobs—that physicians might combine mifepristone with ketoconazole in patients "who are non-responders to Korlym® [monotherapy]." *See* Belanoff Tr. at 264:15-267:2.

4. Teva's Argument that the Package Insert Does No More than "Permit" an Infringing Use Improperly Fails to Address the Package Insert As a Whole and Does Not Raise Any Disputed Facts

Teva further contends that its package insert does not encourage infringement because it only "permits" the co-administration of mifepristone with strong CYP3A inhibitors. Teva Br. at

10. According to Teva, "[i]f a prescriber, exercising her own judgment, decides to [co-administer], it will not be because of anything Teva's label says." *Id*. at 10-11. This unsupported attorney argument lacks merit.

The undisputed factual record indicates that Teva's package insert does far more than simply "permit" an infringing use. Instead, the undisputed content of the package insert allows this Court to infer that Teva has the requisite intent to encourage infringement. Teva does not meaningfully dispute (because it cannot dispute) that Table 3 of its package insert contains clinical trial data indicating how much mifepristone blood serum concentrations will rise as a result of co-administration with strong CYP3A inhibitors. *See* Teva Reply to Corcept SMF at ¶ 32. Teva also does not dispute that Table 3 of its package insert instructs that to treat the patient safely and to avoid a dangerous rise in mifepristone concentration when co-administering the drug with strong CYP3A inhibitors, a "**[d]ose adjustment** [is] **required**." *See id.* (emphasis original). Teva further cannot dispute that its package insert contains one specific set of dose adjustment steps for healthcare practitioners to follow "when necessary" to add a strong CYP3A inhibitor to the treatment regimen of a patient "already being treated with mifepristone tablets." *See id.* at ¶¶ 27, 29. It is further undisputed that those dose adjustment steps directly overlap with the methods claimed in the '214 Patent. These undisputed facts are dispositive of the infringement inquiry. *See* ECF No. 198 at §§ IV(A)-(B); *see also, e.g.*, *Eli Lilly & Co.*, 845 F.3d at 1368-69 (where the proposed package insert contains "instructions [that] are unambiguous on their face" and teach healthcare providers to practice an infringing use, those instructions "encourage or recommend infringement"); *Braintree Labs.*, 688 F. App'x at 910.

Teva's attorney argument that its package insert at most "permits" infringement and that nothing therein actually encourages the practice of the claimed methods does not withstand

scrutiny in view of the clinical safety data and the attendant "required" "[d]ose adjustment" instructions. The data indicate that the claimed methods of treatment—methods persons of skill in the art previously thought were unsafe prior to the publication of the data—are in fact safe when healthcare professionals follow the "required" dose adjustment steps, which read on the asserted patent claims. *See* SMF at ¶¶ 27-32. The Court may infer, as a matter of law, that by seeking approval of a package insert containing both clinical data indicating that the claimed methods are safe ***and*** "required" dose adjustment steps to follow (which directly overlap with the claimed methods) when "necessary" to co-administer mifepristone and strong CYP3A inhibitors, Teva will encourage at least some healthcare professionals to practice the claimed methods. "Finding otherwise would essentially require finding that doctors would not read the [c]linical [data] section of [the package insert]. Such a finding would be contrary to medical practice." *Amarin*, 449 F. Supp. 3d at 1000 (also finding "explicit textual support for Plaintiffs' inducement theory in the Clinical Studies section of the labelling for all Asserted Claims—that a doctor would understand to suggest she should prescribe the drugs in an infringing way.").

Teva does not—because it cannot—dispute the content of its package insert. Its only rejoinder is to claim that "*HZNP* considered and rejected" the infringement argument that Corcept asserts in this case. *See* Teva Br. at 15. More specifically, Teva attempts to analogize this case to *HZNP*, claiming that its "label simply provides guidance to physicians about what to do *if* they decide, in the exercise of their own medical judgment, to co-administer the two drugs." *Id.* at 16. But Teva ignores that in *HZNP*, there was no instruction in the package insert indicating it would ever be "necessary" or "required" to use a second ointment after applying the medication. *Supra* at § II(A)(1). Nor was there was any factual finding—let alone consideration—of clinical safety data that would provide recommendations or encouragement to

practice the claimed methods. *Id.* By contrast, the proposed label here instructs physicians: (1) that there are instances where it may be "necessary" to perform the claimed methods; (2) how to perform each step of the claimed methods; (3) that the claimed methods are "required" when co-administering mifepristone and strong CYP3A inhibitors; and (4) that the claimed methods are safe. *See* ECF No. 198 at §§ IV(A)(1)-(4); *see also supra* at § II(A)(1). Teva's label is therefore much different than what the Federal Circuit encountered and "considered" in *HZNP*.

Teva also contends that it is "irrelevant" that the non-infringing instructions in the *HZNP* case were directed to patients, whereas the infringing dose titration instructions (and safety data) in Teva's label are directed to healthcare professionals. *See* Teva Br. at 16. Teva's argument is incorrect. As an initial matter, Teva ignores *Amarin Pharma v. West-Ward Pharmaceuticals* (cited in Corcept's opening memorandum), where the court expressly determined that the question of how and whether a "***doctor*** would look at the clinical studies portion of the labelling because of that doctor's medical training and experience would ***not*** [be answered by] the situation addressed in *HZNP Medicines*, where the court was considering whether a ***patient*** would infringe." 407 F. Supp. 3d 1103, 1112 n.4 (D. Nev. 2019) (emphasis added). This of course makes perfect sense—a warning directed to a patient to wait for their medicine to dry before applying sunscreen or bug spray is not a recommendation or encouragement to apply sunscreen or bug spray in the first place. But providing medical professionals with a package insert containing both "***required***" dose adjustment instructions for co-administration of two potentially dangerous drugs and clinical data evidencing the safety of those particular dosages is a recommendation and an encouragement to follow those instructions. *See, e.g.*, *Sanofi*, 875 F.3d at 645; *Vanda*, 887 F.3d at 1131; *Amarin Pharma*, 449 F. Supp. 3d at 1000.

Further, Teva's discussion of its package insert—and its application of (its version of) the facts to the *HZNP* case—also deliberately omits all mention of certain sections of its package insert, such as Table 3, including the safety data and required dosage instructions set forth therein. Unlike the HZNP label's passing reference to applying sunscreen or bug spray, Teva's package insert here reports clinical trial results indicating that the claimed methods are safe, and are "required" to be used in the certain circumstances. Put simply, a party cannot obtain or defeat a finding of summary judgment based upon its attorneys' ***deliberately selective*** interpretation of the factual record. *See Glaverbel Societe Anonyme v. Northlake Mktg. & Supply, Inc.*, 45 F.3d 1550, 1562 (Fed. Cir. 1995) ("There must be sufficient substance, other than attorney argument, to show that the issue requires trial."); *see also, e.g.*, *Robbins v. Port of $ale, Inc.*, No. 12-CV-90, 2018 WL 5024920, at *2 n.31 (V.I. Super. Ct. Oct. 10, 2018) ("Counsel is not at liberty to ignore the record and finagle a version of 'undisputed facts' that is neither undisputed nor factual for surviving summary judgment."); *Sec. & Data Techs., Inc. v. Sch. Dist. of Philadelphia*, 145 F. Supp. 3d 454, 470 (E.D. Pa. 2015) (denying defendants' motion for summary judgment where their "characterization of the summary judgment record is not accurate and ignores evidence proffered by [plaintiff]."). Teva's attempt to cross-move for summary judgment on its selective consideration of the factual record should likewise be rejected.

Moreover, Teva's infringement expert (Dr. Peter Snyder) does not discuss the package insert's clinical data in his expert report, nor does he address the instruction in Table 3 that the claimed dose adjustment is "required."[5] [redacted]

[5] And because he failed to provide any opinions on the clinical pharmacology section or the label as a whole in his report or at deposition, he is precluded from later offering any such opinions in this case.

[redacted] To be sure, the Court need not rely on this expert testimony to grant Corcept's motion. However, the fact that Teva's expert has neither considered nor offered an opinion about the import of Table 3 means that the Court will not have to decide a factual dispute regarding how doctors will interpret the data or instructions contained therein at trial; Teva cannot present such evidence for the first time at trial. *See, e.g.*, *Changzhou Kaidi Elec. Co. v. Okin Am., Inc.*, 112 F. Supp. 3d 330, 339 (D. Md. 2015) (holding that a litigant "may not introduce at trial testimony, other evidence, or argument concerning … theories not contained" in its expert's report); *Sunovion Pharms. Inc. v. Dey Pharma., L.P.*, No. 06-113, 2012 WL 6858144, at *2 (D. Del. Jan. 27, 2012) (explaining it is improper to introduce expert testimony for the first time at trial regarding "subject matter that is neither mentioned nor referenced anywhere in an expert's report.").

C. The Other Authorities Teva Relies Upon Do Not Support the Cross-Motion

None of the other cases relied upon by Teva throughout its brief are analogous on the facts. For example, Teva contends that *Grunenthal GmbH v. Alkem Laboratories Ltd.*, 919 F.3d 1333 (Fed. Cir. 2019) "likewise demonstrates that summary judgment of non-infringement is appropriate here." Teva Br. at 16-17. Teva is incorrect, as *Grunenthal* is readily distinguishable. There, the patent claimed a method of treating "polyneuropathic pain" with tapentadol hydrochloride. *See* 919 F.3d at 1336. However, the defendants expressly carved this indication

[6] On the other hand, Corcept's infringement expert (clinical endocrinologist Dr. Ty Carroll) has provided unrebutted testimony in this case that the clinical pharmacology section of Teva's package insert "provides clinical data that indicate it is safe to co-administer 600 milligrams mifepristone in combination with a strong CYP3A inhibitor like ketoconazole." *See* Teva Exhibit 3 at 125:16-126:16.

from their proposed generic labels.[7] *See id.* at 1338-39. On this basis, the Federal Circuit held that "the proposed ANDA labels do not specifically encourage use of tapentadol hydrochloride for treatment of polyneuropathic pain." *Id.* at 1339. In this case, on the other hand, Teva has not carved out the patented method from its package insert.

Teva further relies on several district court cases that it contends "likewise demonstrate that [it] is not liable for inducement." Teva Br. at 17. Yet, these cases are easily distinguishable. Teva first relies on *Shire, LLC v. Amneal Pharmaceuticals, LLC*, No. 11-3781, 2014 WL 2861430 (D.N.J. June 23, 2014), claiming that it is "particularly instructive." Teva Br. at 17. There, the Court found that a statement in the package insert that "the [generic drug] products may be taken 'with or without food'" did not encourage infringement of a method of treating ADHD by administering a given drug product "with intake of food." *See* 2014 WL 2861430, at *4-5. Teva claims that its "non-infringement position here is even stronger than [the defendant's position] in *Shire*," because its "proposed label is not merely 'indifferent' to whether a strong CYP3A inhibitor should be co-administered with mifepristone; instead, the label warns *against* such co-administration unless medically necessary." Teva Br. at 18. This argument fails for two reasons. As an initial matter, simply because Teva's label advises caution when co-administering mifepristone and strong CYP3A inhibitors is not, as a matter of law, a warning against the combination, especially where prescribers are instructed that the patented dose adjustments are "required" in such instances. For instance in *Vanda*, the Federal Circuit held that even though the label stated that "[c]aution is warranted when prescribing iloperidone [to the

[7] Although a generic drug product is generally required to have the same labeling as the branded drug product it seeks to copy, in certain circumstances the Hatch Waxman Act (specifically, 21 U.S.C. § 355(j)(2)(A)(viii)) allows the generic sponsor to file what is known as a "section viii certification" and remove or "carve out" certain indications of use from the generic drug product labeling to avoid patent (or other regulatory) exclusivities.

claimed patient population]," the inclusion of language in the package insert that "instructs users to perform the patented method" would encourage infringement. 887 F.3d at 1122, 1132. Moreover, Teva's label is not merely "indifferent" to whether the claimed method is performed; as set forth above, Teva's label instructs in no uncertain terms that the claimed methods of treatment are "**required**" when it is "necessary" to co-administer a strong CYP3A inhibitor with Teva's mifepristone product. *See* Teva Reply to Corcept SMF at ¶¶ 29, 32.

Teva's reliance on *Niazi Licensing Corp. v. St. Jude Med. S.C., Inc.*, No. 17-5096, 2021 WL 1111074 (D. Minn. Mar. 23, 2021) is also unavailing. There, the Court explained that defendant St. Jude's written instructions do not "encourage, recommend, or promote infringement for at least three reasons. First, [the] instructions substantively differ from steps of the patented method in several ways…. Second … there is no evidence that St. Jude has instructed its customers to perform those steps in the precise order listed in Claim 11 of the '268 Patent. Third, several steps in St. Jude's written instructions are optional, which a physician may perform '[i]f desired.'" *Id.* at *7. Here, by contrast, there is no dispute that: (1) the instructions set forth in Table 1 of Teva's package insert mirror the claimed method; (2) Table 1 instructs physicians to perform each and every step of the claimed methods in the same order as in the asserted claims, and (3) Table 3 states these "[d]ose adjustment" steps are "**required**" when the need arises to co-administer mifepristone with strong CYP3A inhibitors. *See* Teva Reply to Corcept SMF at ¶¶ 27, 32.

Teva also relies on *Novartis Pharm., Corp. v. Wockhardt USA LLC*, No. 12-3967, 2013 WL 5770539 (D.N.J. Oct. 23, 2013). But the facts of *Novartis* are facially distinguishable from those of this case. In *Novartis*, the defendants sought FDA approval to market their generic products "only for treatment of Paget's disease—a non-patented use." *See id.* at *7. The

defendants submitted "section viii certifications specifically carving out references to osteoporosis—the patented use." *Id.* Therefore, the Court held that the defendants' proposed package inserts did not encourage infringement of methods of treating osteoporosis where their "proposed labels do not mention osteoporosis." *Id*. at *9. As set forth above, those are not the facts of this case—Teva has not carved out any instructions related to the claimed methods from its label.

Teva claims that *Otsuka Pharmaceutical Co. v. Torrent Pharmaceuticals Ltd.*, 99 F. Supp. 3d 461 (D.N.J. 2015) is "also on point." Teva Br. at 18. Like the *Grunenthal* and *Novartis* cases on which Teva also relies, *Otsuka* found insufficient evidence of intent to induce infringement where the defendants' "proposed labels have 'carved out' the indication covered by the [asserted] patent." *See* 99 F. Supp. 3d at 476. In other words, "[c]ritically absent from each proposed label is *any* indication that the generic aripiprazole products should be used for adjunctive treatment of major depressive disorder, the primary indication for the [asserted] patent." *See id* . at 485. As set forth above, those are not the facts of this case—Teva has not carved out any instructions related to the claimed methods from its label.

Finally, citing *United Therapeutics Corp. v. Sandoz, Inc.*, No. 12-1617, 2014 WL 4259153 (D.N.J. Aug. 29, 2014), Teva further claims that "[t]here can be no inducement under [the] circumstances" presented in this case. Teva Br. at 11. But Teva's reliance on *United Therapeutics* is also misplaced. There, the parties agreed that infringement of the claimed method would require concomitant use of the proposed generic product with a "Sterile Diluent." *See* 2014 WL 4259153, at *13. However, the defendant (Sandoz) had carved out such instructions from its proposed package insert, "which eliminated any mention of the Sterile Diluent." *Id.* The patentee nonetheless argued that some physicians may decide, based on

certain warnings in Sandoz's label, to "search for and review" third-party references that recommended use of the Sterile Diluent and elect to prescribe the carved-out method based on those external sources. *Id.* at *17. The court held that this "scholarly scavenger hunt" would not induce infringement; intent to induce could not be found where the patented method was carved out of the proposed generic label and the actual instructions to infringe were found not in the label itself, but in third-party journal articles. *Id.* at *19-21. That is not the case here. There is no carve-out in Teva's label, and a healthcare professional would not have to look outside of Teva's package insert to determine: (1) that there are instances where it may be "necessary" to perform the claimed methods; (2) how to perform each step of the claimed methods; (3) that the claimed methods of treatment are "required" when co-administering mifepristone and strong CYP3A inhibitors; and (4) that the claimed methods of treatment are safe.

D. [redacted]

Finally, despite relying heavily on carve-out cases to evade infringement, Teva has no substantive response to the simple fact that, here, [redacted] Instead, Teva concludes its brief by accusing Corcept of engaging in an "abuse of the FDA's 'use code' system." Teva Br. at 23-24. Corcept disagrees, but will not burden the Court with a point-by-point response to these allegations, which is unnecessary to resolve the instant motion. It is worth noting, however, that if Teva truly believed Corcept had committed an "abuse" of the FDA use code system with respect to the '214 Patent, it could have asserted a counterclaim under 21 U.S.C. § 355(j)(5)(C)(ii)(I) "to force correction of a use code that inaccurately describes the brand's patent as covering a particular method of using the drug in question." *Caraco Pharm. Lab'ys,*

Ltd. v. Novo Nordisk A/S, 566 U.S. 399, 404 (2012). That Teva has not done so speaks volumes about the merits of its accusation.

[redacted]

Likewise, Teva could have chosen to file a Paragraph III Certification and waited until the '214 Patent expires before deciding to market its generic mifepristone product, but chose not to. *See* ECF No. 198 at 29. The case law makes clear that generic drug applicants cannot "include [in their labels] the very titration schedule recited in [the claims of the asserted patent]" and then argue (as Teva does here) that "permissive language in the labels allows them to escape induced infringement." *See Forest*, 206 F. Supp. 3d at 976-77. Instead, "[t]he crux of induced infringement is [whether] defendants have included the exact [dose] titration [method] as claimed in the [asserted] patent and have made no effort to remove the titration schedule from the labels or submit a Paragraph III certification and wait for the asserted patents to expire." *Id.* at 977-78.

The Court can readily infer [redacted] that it intends for healthcare professionals to follow all the instructions included in its label, including those that overlap with the claimed methods. [redacted] Teva instead seeks to copy Corcept's product, and it seeks to provide healthcare professionals with instructions for using that product that indisputably teach each and every step of the claimed method. Teva's label indisputably teaches an infringing use, provides clinical data indicating that the infringing use is safe, and tells healthcare providers that "when necessary" to combine mifepristone and strong CYP3A inhibitors they are "required" to

practice the claimed dose adjustment methods. [redacted] This is more than sufficient evidence from which to infer Teva's intent as a matter of law, without the need for trial. *See, e.g.*, *Forest*, 206 F. Supp. 3d at 976-77.

III. CONCLUSION

For the foregoing reasons, Corcept respectfully requests that the Court enter summary judgment of infringement of claims 1-13 of the '214 Patent and deny Teva's cross-motion for summary judgment of non-infringement.

Dated: July 9, 2021

Respectfully submitted,

s/ William C. Baton

Charles M. Lizza
William C. Baton
Sarah A. Sullivan
SAUL EWING ARNSTEIN & LEHR LLP
One Riverfront Plaza, Suite 1520
Newark, NJ 07102-5426
(973) 286-6700
clizza@saul.com
wbaton@saul.com

Attorneys for Plaintiff
Corcept Therapeutics, Inc.

Of Counsel:

F. Dominic Cerrito
Eric C. Stops
Daniel C. Wiesner
John Galanek
Nicholas A. LoCastro
QUINN EMANUEL URQUHART & SULLIVAN, LLP
51 Madison Avenue, 22nd Floor
New York, New York 10010
(212) 849-7000